

NATURE OF CHARGE: On or about June 2, 11, 12, 16, and 30, 1953, while a number of *methylparafynol capsules*, *secobarbital sodium capsules*, and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were being held for sale at Western Drugs, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: February 15, 1954. The defendant having entered a plea of *nolo contendere*, the court fined him \$250, plus costs.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

4386. Misbranding of whole pituitary capsules and anterior pituitary tablets.
U. S. v. 279 Bottles, etc. (F. D. C. No. 36455. Sample Nos. 52127-L, 52130-L, 52162-L, 52163-L.)

LIBEL FILED: March 18, 1954, Southern District of New York.

ALLEGED SHIPMENT: On or about December 29, 1953, and January 19, 1954, by Armour Laboratories, from Bradley, Ill.

PRODUCT: 279 bottles of *whole pituitary capsules* and 36 bottles of *anterior pituitary tablets* at New York, N. Y.

LABEL, IN PART: (Bottle) "100 - 1 Grain (60 mg.) List 3100 Whole Pituitary Capsules Each Capsule Contains 1 Grain (60 mg.) Of Whole Calf Pituitary Powder Caution: Federal law prohibits dispensing without prescription. Directions For Use Will Be Supplied To Physicians Upon Request * * * The Armour Laboratories A Division Of Armour And Company, Chicago, Illinois" and "Armour 100 - 5 Grain Anterior Pituitary Tablets Each Tablet Contains 5 Grains Anterior Pituitary * * * Caution: To be dispensed only by or on the prescription of a physician."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use.

Further misbranding, Section 503 (b) (4), the articles were drugs to which Section 503 (b) (1) did not apply, and the labels of the drugs, prior to dispensing, bore a caution against dispensing the drugs without a prescription.

DISPOSITION: April 22, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

4387. Misbranding of anterior pituitary injectable and whole ovarian injectable.
U. S. v. 44 Vials, etc. (F. D. C. No. 36442. Sample Nos. 40022-L, 40023-L.)

LIBEL FILED: March 18, 1954, Southern District of California.

ALLEGED SHIPMENT: On or about October 6 and November 13, 1953, by the Difco Laboratories, from Detroit, Mich.

PRODUCT: 44 vials of *anterior pituitary injectable* and 71 vials of *whole ovarian injectable* at Glendale, Calif., in possession of the Nelson Pharmacal Co.

*See also No. 4381.

**See also Nos. 4381, 4386.

~~RESULTS OF INVESTIGATION: The consignee relabeled the products after their shipment in interstate commerce.~~

LABEL, IN PART: (Vial) "Nelson 30 cc. Anterior Pituitary Injectable * * * List No. 270 * * * Each cc. contains the water soluble heat stable, extractives derived from (18½ gr.) 1.2 Gm. fresh anterior pituitary lobes. * * * Preservative: Chlorobutanol (chloroform derivative) 0.5%" and "Nelson 30 cc. Whole Ovarian Injectable * * * List No. 280 * * * Each cc. contains the water soluble heat stable, extractives derived from 40 gr. of fresh whole ovarian tissue. Preservative: Chlorobutanol (chloroform derivative) 0.5%."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use. The articles were misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: April 8, 1954. Default decree of condemnation and destruction.

4388. Misbranding of ultrasonic device. U. S. v. 1 Device, etc. (F. D. C. No. 34464. Sample No. 40623-L.)

LABEL FILED: January 15, 1953, Western District of Washington.

ALLEGED SHIPMENT: On or about June 5, 1952, by R. J. Lindquist, from Los Angeles, Calif.

PRODUCT: 1 *ultrasonic device* at Seattle, Wash., together with 1 copy of a two-page translation from Pohlmon "Die Ultraschalltherapie," 1 copy of an instruction booklet designated "Lindquist 'Chronosonic' Ultrasound Generator Model 401," and 1 copy of printed matter designated "Bulletin * * * Ultrasonics In Therapy."

The above-mentioned instruction booklet indicated that the device would give off ultrasonic energy at approximately 1 megacycle frequency and at a maximum energy intensity output of 2 watts per square centimeter of "head."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned translation and in the above-mentioned bulletin accompanying the device were false and misleading. The statements represented and suggested that the device would provide an adequate and effective treatment for abscesses, adnexitis, angina pectoris, arthritis, asthma, Bechterew's disease, bed-wetting, bronchitis (bronchiectasis), bursitis, causalgia, colecystitis, colesystopathic, coccygodynia, colitis, coxarthrosis, diphtheric bacilli carriers, glands (tumefaction), Dupuytren's contracture, dysbasia, elephantiasis, eczema, endangitis obliterans, epicondylitis, epilepsy, erythema nodosa, erythromelalgia, fistula, furuncle, carbuncle, joint effusion, gingivitis, urethral stricture, skin carcinoma, hemiplegia, herpes zoster, hypertonia essential, infiltrations, intercoastal neuralgia, induratio penis plast, ischialgia, lockjaw, lumbago, lymphadenitis, mastitis, Meniere's disease, multiple sclerosis, myalgia, myelitis, scar contraction, neuralgia, neuritis, neuroma after amputation, osteomyelitis, ostitis, periostitis, panaris, paradentosis, parotitis, paronychia, parulis, periarthrititis, phlegmon, polyarthrititis, postoperative pain, prostatitis, pruritus, pulpitis, Raynaud's disease, rheumatism, X-ray ulcers, scalenus syndrom, sweat glands abscess, scleroderma, sinusitis, spondylosis, sudek'sche dystrophy, tendovaginitis, thrombophlebitis, tonsillitis, trigeminus neuralgia, tuberculosis, tumors, ulcer cruris, gastrointestinal ulcers, warts, dental granuloma, cellulitis, radiculitis, kieferhoehlenentzuendung, and nebenhoehlenentzuendung. The device would not provide an adequate and effective treatment for such conditions.